APPENDIX 14

EVALUATION ROUTES

There are four (4) types of methods of evaluation for product registration.

1) **Full Evaluation (Standard Pathway)**

2) **Full Evaluation (Conditional Registration)**
   a) This applies to new registration applications for New Drug Products and Biologics.
   b) At the point of submission, the product must be registered in at least one (1) Drug Control Authority (DCA) reference agency.
   c) A conditional registration does not apply to additional indications submitted post-registration. However, the approval of additional indication with less than comprehensive clinical data may be considered on a case-to-case basis.
   d) A conditional registration is valid for two (2) years. Thereafter, the conditional registration may be renewed two (2) times (with the possibility of two (2) extensions of two (2) years each).
   e) For further details, refer to *Guidelines on Conditional Registration for New Chemical Entities and Biologics*.
   f) For medicinal products or vaccines to be used during disaster:
      - The guideline must be read in conjunction with *Guidance and Requirements on Conditional Registration of Pharmaceutical Products During Disaster*.
      - The validity of conditional registration is one year. Thereafter, the conditional registration may be renewed two (2) times (with the possibility of two (2) extensions of one (1) year each).
      - All registration applications for pharmaceutical products during disaster that fulfil the eligibility conditions shall be automatically given **priority review** status and shall be processed within **70 working days*** from the date the complete application is received. If the product has been conditionally approved or given emergency use authorization or listing by any DCA reference countries or WHO (hereby referred as Recognition Pathway), the time taken for reviewing process would be significantly shortened.

      *Note: The timeline has been revised from 120 working days to **70 working days**.

References:

i. Directive No. 15, 2018, *BPFK/PPP/07/25 (15) Jld.2*: *Direktif Untuk Melaksanakan* Guidelines on Conditional Registration for New Chemical Entities and Biologics (30 May 2018)
ii. Directive No. 18, 2020, *NPRA.600-1/9/13(9)*: *Direktif Berkenaan Pelaksanaan Pendaftaran* Fast-Track *Bersyarat Untuk Produk Farmaseutikal Semasa Bencana* (14 December 2020)
iii. Directive No. 15, 2021, *NPRA.600-1/9/13(25)*: *Direktif Berkenaan Pelaksanaan Pendaftaran Bersyarat Produk Farmaseutikal Semasa Bencana Secara Recognition* (12 July 2021)
iv. *NPRA.600-1/9/12 (14): Pekeliling Berkenaan Pindaan Kriteria Bagi Produk Yang Layak Memohon Pendaftaran Fast Track Bersyarat Untuk Produk Farmaseutikal Semasa Bencana* (20 June 2022)

3) **Full Evaluation via Facilitated Registration Pathway (Abbreviated and Verification Review)**

- This applies to New Drug Products, Generic Medicines, and Biologics, including cell and gene therapy products (CGTPs).
- Abbreviated Review involves a limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements, while relying on prior assessment and inspection outcomes from a reference authority or trusted institution to inform the local decision. This applies to a product that has been evaluated and approved by:

  i) WHO Collaborative Registration Procedure (CRP)
     a) Products authorised by WHO Stringent Regulatory Authorities (SRAs)/ WHO Listed Authorities (WLA)
     b) WHO prequalified medicines and vaccines

  ii) Products approved by any of the following regulatory agencies*
     a) European Medicines Agency (EMA)
     b) Health Canada
     c) Pharmaceuticals and Medical Devices Agency (PMDA), Japan
     d) Swissmedic, Switzerland
     e) Therapeutic Goods Administration (TGA), Australia
     f) United Kingdom Medicines and Healthcare products Regulatory Agency (UK MHRA)
     g) United States Food and Drug Administration (US FDA)

     *at least one agency approval or more

- Verification Review is a review of the sameness of the product dossier to ensure that the medical product is the same as the one that has been assessed by ASEAN Joint Assessment. This applies to a product that has been evaluated and approved by ASEAN Joint Assessment (JA) procedure.

- Refer to *Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023* (Effective 1 January 2024)

Reference: Directive No. 13, 2023, *NPRA.600-1/9/13 (31)Jld.1*: *Direktif Berkenaan Pengemaskinian dan Pelaksanaan Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023* (16 November 2023)

4) **Abridged Evaluation**

Methods of Evaluation According to Product Category:

No.	Product Category	Method of Evaluation	
		Full Evaluation	**Abridged Evaluation**
1.	New Drug Products	√	Not Applicable
2.	Biologics	√	Not Applicable
3.	Generics (Scheduled Poison)	√	Not Applicable
4.	Generics (Non-Scheduled Poison) [or known as OTC]	* All products from this category, unless stated in Abridged Evaluation	Includes, but not limited to the following: • Antiseptics/ skin disinfectants; • Locally acting lozenges/ pastilles; • Topical analgesic/ counter-irritants; • Topical nasal decongestants; • Emollient/ demulcent/skin protectants; • Keratolytics; • Anti-dandruff; • Oral care; • Anti-acne; • Medicated plasters/patch/pad; and • Topical antibacterial.
5.	Health Supplements a) General or Nutritional Claims	Not Applicable	√
	b) Functional Claims (Medium)	Not Applicable	√
	c) Disease Risk Reduction Claims (High)	√	Not Applicable
6.	Natural Products	Not Applicable	√
7.	Natural Products with Therapeutic Claim	√	Not Applicable